



*Billing Code 3410-34

DEPARTMENT OF AGRICULTURE

December 8, 2011

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, D.C. 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control

number.

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Animal Plant and Health Inspection Service

TITLE: Virus-Serum-Toxin Act and Regulations in 9 CFR, Subchapter E, Parts 101-124

OMB CONTROL NUMBER: 0579-0013

SUMMARY OF COLLECTION: The Virus-Serum-Toxin Act (37 Stat. 832-833, 21 U.S.C. 151-159) gives the United States Department of Agriculture, the Animal and Plant Health Inspection Service (APHIS) the authority to promulgate regulations designed to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products. A veterinary biological product is defined as all viruses, serums, toxins, and analogous products of natural or synthetic origin. In order to effectively implement the licensing, production, labeling, importation, and other requirements, APHIS employs a number of information gathering tools such as establishment license applications, product license applications, product permit applications, product and test report forms and field study summaries.

NEED AND USE OF THE INFORMATION: APHIS uses the information collected as a primary basis for the approval or acceptance of issuing licenses or permits to ensure veterinary biological products that are used in the United States are pure, safe, potent, and effective. Also, APHIS uses the information to monitor the serials for purity, safety, potency and efficacy that are produced by licensed manufacturers prior to their release for marketing. Failing to collect this information would severely cripple APHIS' ability to prevent harmful veterinary biologics from being distributed in the United States.

DESCRIPTION OF RESPONDENTS: Business or other for profit; State, Local or Tribal Government

NUMBER OF RESPONDENTS: 202

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FREQUENCY OF RESPONSES: Recordkeeping; Reporting: On occasion

TOTAL BURDEN HOURS: 74,386

Animal and Plant Health Inspection Service

TITLE: Scrapie in Sheep and Goats; Interstate Movement Restrictions and Indemnity Program

OMB CONTROL NUMBER: 0579-0101

SUMMARY OF COLLECTION: Under the Farm Security and Rural Investment Act of 2002, P.L. 107-71, subtitle E, Animal Health Protection, Section 10401-10418, the Secretary of Agriculture, in order to protect the agriculture, environment, economy, and health and welfare of the people of the United States by preventing, detecting, controlling, and eradicating diseases and pests of animal, is authorized to cooperate with foreign countries, States, and other jurisdictions, or other person, to prevent and eliminate burdens on interstate commerce and foreign commerce, and to regulate effectively interstate commerce and foreign commerce. Scrapie is a progressive, degenerative and eventually fatal disease affecting the central nervous system of sheep and goats. Its control is complicated because the disease has an extremely long incubation period without clinical signs of disease, and there is no test for the disease and or known treatment. The Animal and Plant Health Inspection Service (APHIS) restricts the interstate movement of certain sheep and goats to help prevent the spread of scrapie. APHIS has regulations at 9 CFR Part 54 for an indemnity program to compensate owners of sheep and goats destroyed because of scrapie.

NEED AND USE OF THE INFORMATION: APHIS will collect information using cooperative agreements; applications from owners to participate in the Scrapie Flock Certification Program; post-exposure management and monitoring plans; scrapie test records; application for indemnity

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payments; certificates, permits, and owner statements for the interstate movement of certain sheep and goats; application for premises identification numbers; and applications for APHIS-approved eartags, backtags, or tattoos, etc. Without this information APHIS' efforts to more aggressively prevent the spread of scrapie would be severely hindered.

DESCRIPTION OF RESPONDENTS: Business or other for-profit; Not for Profit; and State, Local, or Tribal Government

NUMBER OF RESPONDENTS: 112,000

FREQUENCY OF RESPONSES: Recordkeeping; Reporting: On occasion

TOTAL BURDEN HOURS: 897,030

Ruth Brown
Departmental Information Collection Clearance Officer

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